

Arguments/Remarks

Claims 1, 2, 4 and 5 are pending in the present application. Claim 4 was cancelled since it no longer retained antecedent basis to the currently amended claims. Applicants reserve the right to file one or more divisional applications which claim the deleted and previously non-elected subject matter.

Claims 1 and 2 have been amended to limit the definition of Z to carbon.

Obviousness-type Double Patent Rejection

I. Claims 1, 2, 4 and 5 were rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over Claims 11-18 and 21 of US Patent No. 7,358,266.

Nothing in US Patent No. 7,358,266 teaches or suggests a double bond between C2 and C3, and R³ equal to hydrogen. In *Takeda Chemical vs. Alphapham* (Fed Cir., No. 06-1329, 2007), the court states that "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." The court found that because there was no motivation in the prior art for selecting the earlier compound as the lead compound for research, the burden for proving a prima facie case of obviousness based on a structurally similar compound was not met.

"Our case law concerning prima facie obviousness of structurally similar compounds is well-established. We have held that "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness." *Dillion*, 919 F.2d at 691. In addition to structural similarity between the compounds, a *prima facie case of obviousness also requires a showing of "adequate support in the prior art" for the change in structure.* *In re Grablak*, 769 F.2d 729, 731-32 (Fed Cir. 1985).

We elaborated on this requirement in the case of *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995), where we stated that "[n]ormally a prima facie case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound." That is so because close or established "[s]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds." *Id.* A known compound may suggest its homolog, analog, or isomer because such compounds "often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." *Id.* We clarified, however, that in order find a prima facie case of unpatentability in such instances, a *showing that the "prior art would have suggested making the specific molecular*

modifications necessary to achieve the claimed invention" was also required. Id. (citing *In re Jones*, 958 F.2d 247 (Fed Cir. 1992), 919 R 2d 688, *Grabiak*, 769 F.2d 729; *In re Lalu*, 747 F.2d 703 (Fed Cir. 1984)).

That test for prima facie obviousness for chemical compounds is consistent with the legal principles enunciated in KSR. While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. *KSR*, 127 S.Ct. at 1731. Moreover, the Court indicated that there is "no necessary inconsistency between the idea underlying the TSM test and the Graham analysis." *Id.* As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry. *Id.* Thus, *In cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."* (Emphasis added) *Takeda Chemical vs. Alphapharm* (Fed Cir., No. 06-1329, 2007)

The Examiner provided no specific evidence that there existed a reason, based on what was known at the time of the invention, to make the chemical modifications necessary to achieve the claimed compounds. It is important to note that all of the compounds disclosed in the '266 patent have a single bond between C2 and C3 and R³ is equal to hydroxy. Clearly, the '266 patent does not teach how to make or use compounds containing both a double bond between C2 and C3 and R3 equal to hydrogen. Hence, Applicants respectfully submit that the disclosure of the '266 patent does not render the presently claimed compounds obvious; therefore, the statutory obviousness-type double patenting rejection should be withdrawn.

35 USC §102 Claim Rejections

I. Claims 1, 2 and 4 were rejected under 35 USC §102(b) as being anticipated by Hoefle et al (US Patent No 6,288,23).

Cancellation of Claim 4 rendered this rejection moot with respect to that claim. Applicants respectfully submit that the amendment of Claims 1 and 2 to those compounds where Z is carbon renders this reject moot with respect to those claims as well since Hoefle does not teach or disclose any compounds having a cyclopropyl group at the Z position.

Applicants respectfully submit that Claims 1, 2 and 5 are in condition for allowance based on the amendments submitted herewith and the arguments presented above.

Respectfully submitted,

Novartis Institutes for BioMedical Research, Inc.
220 Massachusetts Avenue
Cambridge, MA 02139
(617) 871-5098

/Arlene K. Musser/
Arlene K. Musser
Attorney for Applicants
Reg. No. 37,895

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